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| 09/807,949      | 08/09/2001  | Jan Zavada           | D-0021.5C-1         | 9458             |

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EXAMINER

YAEN, CHRISTOPHER H

ART UNIT PAPER NUMBER

1642

DATE MAILED: 10/06/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/807,949

Applicant(s)

ZAVADA ET AL.

Examiner

Christopher H Yaen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 June 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 20-27 and 31-44 is/are pending in the application.
- 4a) Of the above claim(s) 20-27, 43 and 44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 31-42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All   b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      6) ☐ Other: \_\_\_\_\_

### **SUPPLEMENTAL DETAILED ACTION**

1. The office action mailed on 9/10/2003 (paper no. 13) was inadvertently marked as FINAL. This supplemental office action corrects the Office action cover sheet to indicate the status as NON-FINAL.
2. The amendment filed 6/16/2003 (paper no. 12) is acknowledged and entered into the record.
3. Claims 20-27 and 31-44 are pending, claims 20-27 and 43-44 are withdrawn from further consideration as being drawn to a non-elected invention.
4. This application contains claims 20-27, and 43-44 drawn to an invention nonelected with traverse in Paper No. 9. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.
5. Claims 31-42 are examined on the record.

### ***New Arguments***

#### ***Claim Rejections - 35 USC § 112, 2<sup>nd</sup> paragraph***

6. Claims 31-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
7. Claim 31 recites the limitation of "stringent hybridization", of which the specification discloses as a "relatively low salt and/or high temperature conditions" (see page 23). One of skill in the art cannot adequately determine from the specification

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what type of hybridization is encompassed by this definition, as such the metes and bounds of the term cannot be determined.

***Claim Rejections - 35 USC § 112, 1<sup>st</sup> paragraph***

8. Claims 31-42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification has only set forth the sequence of SEQ ID No: 1 and is therefore not commensurate in scope to claims that read on nucleotide sequences that hybridize to the complement of SEQ ID No: 1.

*Vas-Cath Inc. V. Mahurkar*, 19 USPQ2d 1111, clearly states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*.” (See page 1117). The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115).

With the exception of SEQ ID NO:1, the skilled artisan cannot envision the detailed structure of the encompassed polynucleotides that hybridize to the complement of SEQ ID No: 1 because the molecules identified have not been characterized or associated with any structural or functional properties and therefore conception is not

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achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The sequence itself is required wherein there is a correlated functional relationship. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

The findings of *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412) are clearly applicable to the instant rejection. The court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

Support for nucleic acids which hybridizes to the complement of SEQ ID No: 1 is provided in the specification on page 23 lines 4-31 where it is disclosed that "slightly modified nucleotide sequences will be found or can be modified" and "DNA or RNA having equivalent codons is considered within the scope of the invention...as well as those nucleic acid sequence that would hybridize" to said nucleic acid sequences.

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However, no disclosure, beyond the mere mention of allelic variants is made in the specification. This is insufficient to support the generic claims as provided by the Interim Written Description Guidelines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645.

Therefore only an isolated sequence of SEQ ID No: 1 meets the written description provision of 35 USC 112, first paragraph.

***Claim Rejections - 35 USC § 112, 1<sup>st</sup> paragraph***

9. Claims 31-42 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of identifying MN75, MN7, MN9, and MN12 antibodies that bind to a specific site on the MN protein, does not reasonably provide enablement for a method of identifying any and all organic or inorganic molecules capable of binding to the MN protein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or practice the invention commensurate in scope with these claims.

The claims are drawn to a method of identifying an organic or inorganic molecule that binds to a specific site on a MN protein comprising testing organic or inorganic molecules in a cell adhesion assay, and identifying molecules that inhibit the adhesion of cells to the MN protein.

The art teaches that not all antibodies directed against the MN protein are capable of inhibiting the adhesion of MN protein to cells. One such example is Zavada *et al* (cited previously) wherein it is disclosed that an antibody directed against the MN protein was unable to inhibit the binding of NIH3T3 cells to the MN protein, and was

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only effective upon pre-incubation with SAC. Furthermore, protein chemistry is probably one of the most unpredictable areas of biotechnology. For example, conservative replacement of a single "lysine" residue at position 118 of acidic fibroblast growth factor by "glutamic acid" led to the substantial loss of heparin binding, receptor binding and biological activity of the protein (Burgess et al., J of Cell Bio. 111:2129-2138, 1990). In transforming growth factor alpha, replacement of aspartic acid at position 47 with alanine or asparagine did not affect biological activity while replacement with serine or glutamic acid sharply reduced the biological activity of the mitogen (Lazar et al. Molecular and Cellular Biology 8:1247-1252, 1988). These references demonstrate that even a single amino acid substitution or what appears to be an inconsequential chemical modification will often dramatically affect the biological activity and characteristic of a protein.

The specification has demonstrated the use of several antibodies directed against the MN protein but has failed to disclose the identification or any other organic molecule or inorganic molecule that is capable of binding to the MN protein. One of skill in the art would not be able to practice the invention within the scope of the claims because there are a multitude of molecules that are potentially available to one of skill to use or identify as potential inhibitors of the MN protein. Reasonable correlation must exist between the scope of the claims and scope of enablement set forth, and it cannot be predicted from the disclosure how to use any and all organic or inorganic molecules that specifically bind to and inhibit the binding MN protein to cells. Therefore, in view of the lack of predictability of the prior art, the breadth of the claims and the absence of

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working examples, it would require undue experimentation for one skilled in the art to practice the invention as claimed.

**All other rejections are withdrawn in view of the arguments and amendments thereto as set forth in paper no. 12.**

***Conclusion***


10. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 703-305-3586. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Christopher Yaen  
Art Unit 1642  
September 1, 2003

  
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